

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE  
90th Meeting

National Institutes of Health  
900 Rockville Pike, Building 10  
Jack Masur Auditorium, Rockville, MD

AGENDA

Monday, May 1, 2000

10:00 a.m.

**Open Session**

Call to Order: Welcome and Information - Acting Chairman, Robert Califf, M.D.

Conflict of Interest Statement – Joan Standaert, Executive Secretary

NDA 19-901/S028, Altace® (ramapril), King Pharmaceuticals, to be indicated for significant reduction of mortality and morbidity in high-risk patients.

Presentation - King Pharmaceuticals, Inc.

Introduction

Thomas K. Rogers, III, M.S.  
Vice President Regulatory Affairs  
King Pharmaceuticals, Inc.

HOPE Study Designs and Results

Salim Yusuf, D.Phil., M.D.  
HOPE Study Chair  
Director, Population Health Institute  
Director, Division of Cardiology  
Professor of Medicine  
McMaster University, Hamilton, Canada

Clinical Strategies for Renal Protection

Barry M. Brenner, M.D.  
Director, Renal Division  
Brigham & Women's Hospital  
Samuel A. Levine, Professor of Medicine  
Harvard Medical School  
Boston, Massachusetts

HOPE Results in Patients with Diabetes

Hertzel Gerstein, M.D., M.Sc.  
HOPE Study Diabetic Sub-committee Chair  
Dir., Division of Endocrinology & Metabolism  
Dir., Diabetes Care & Research Centre  
Assistant Professor of Medicine  
McMaster University, Hamilton, Canada

Role of DSMB and Implications  
for Public Health

Carl Furberg, M.D., Ph.D.  
Professor, Dept. of Public Health Sciences  
Wake Forest University School of Medicine  
Winston-Salem, North Carolina

1:00 p.m. Lunch

2:00 p.m. Committee discussion and recommendations:

FDA Reviewers:	Primary Medical:	Shari Targum, M.D. Douglas Throckmorton, M.D.
	Secondary Medical:	Shaw Chen, M.D., Ph.D.
	Statistical:	James Hung, Ph.D.
Committee Reviewer:		Joann Lindenfeld, M.D.

Announcements and Adjournment

## CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

90th Meeting

May 1-2, 2000

Oklahoma City, OK 73104

### Participants:

Paul Armstong, M.D.  
Professor, Department of Medicine  
University of Alberta  
251 Medical Science Bldg.  
Edmonton, Alberta, Canada T6C#7

Jeffrey Borer, M.D.  
Director, Div. of Pathophysiology  
Weill Medical College at  
Cornell University  
525 E. 68th St. Rm.F467  
New York, NY 10021

Thomas Flemming, Ph.D.  
Professor and chair  
Department of Biostatistics  
University of Washington  
Box 357232  
Seattle, WA 98195-7232

Cindy Grines, M.D. (May 2)  
Director, Cardiac Catheterization  
Division of Cardiovascular Diseases  
WM Beaumont Hospital  
3601 West 13<sup>th</sup> Street  
Royal Oak, MI 48073

JoAnn Lindenfeld, M.D.  
Professor of Medicine,  
Division of Cardiology  
Univ. of Colorado Health Science Center  
4200 East Ninth Ave. B-130  
Denver, CO 80262

Udho Thadani, M.D. FRCP (May 1)  
Professor of Medicine  
Division of Cardiology  
Oklahoma Univ. Health Sciences Center  
920 S.I. Young Blvd., 5 SP-300

### Invited Guests:

George Bakris, M.D.  
Department of Preventive  
And Internal Medicine  
Rush Medical University  
St. Lukes Hospital  
1725 West Harrison Street  
Chicago, IL 60612

Marc Molitch, M.D.  
member of the E&M Committee (May 1)  
Professor of Medicine  
Northwestern University Medical School  
Center for Endocrinology, Metabolism, and  
Molecular Medicine  
3030 East Chicago Ave  
Tarry Bldg., Room 15-731  
Chicago, IL 60611

CENTER FOR DRUG EVALUATION AND RESEARCH  
CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

90th Meeting

May 1-2, 2000

**CHAIRPERSON**

Packer, Milton, M.D. 06/30/01  
Chief, Division of Circulatory Physiology  
Columbia University  
College of Physicians and Surgeons  
630 West 168th Street  
New York, NY 10032

**EXECUTIVE SECRETARY**

Standaert, Joan C.  
Center for Drug Evaluation and Research  
Food and Drug Administration  
234 Summit Street, Room 117  
Toledo, OH 43604  
419/259-6211 Fax: 419/259-6353

**MEMBERS**

Califf, Robert, M.D. 06/30/00  
Professor of Medicine/Director  
Duke Clinical Research Center  
Duke University Medical Center  
2024 West Main Street, Box 31123  
Durham, NC 27707

DiMarco, John, M.D. 06/30/00  
Professor of Medicine  
Cardiovascular Division  
University of Virginia Hospital  
Hospital Drive, 5th Floor  
Private Clinic, Room 3608  
Charlottesville, VA 22908

Konstam, Marvin, M.D. 06/30/00  
Professor of Medicine  
New England Medical Center  
750 Washington Street, Box 108  
Boston, MA 02111

Roden, Dan, M.D.C.M. 06/30/00  
Vanderbilt University  
Division of Clinical Pharmacology  
532 Medical Research Building 1  
23<sup>rd</sup> Avenue South at Pierce Ave.  
Nashville, TN 37232-6602

**CONSUMER REPRESENTATIVE**

Graboyes, Thomas, M.D. 06/30/01  
Director  
Lown Cardiovascular Center  
21 Longwood Avenue  
Brookline, MA 02146

Piña, Ileana, M.D. 06/30/01  
Director Congestive Heart Failure  
and Transplant Programs  
Case Western Reserve University  
University Hospital of Cleveland  
11100 Euclid Avenue  
Cleveland, OH 44106-5062

April 2000